Summary of the Meeting of the CON Task Force

July 14, 2005

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Task Force Members Present

Commissioner Robert E. Nicolay, CPA, Chairman
Commissioner Robert E. Moffit, Ph.D.
Alan Bedrick, M.D.
Albert L. Blumberg, M.D., F.A.C.R.
Lynn Bonde
Patricia M.C. Brown, Esquire
William L. Chester, M.D.
Annice Cody
Natalie Holland
Carlessia A. Hussein, DrPH
Adam Kane, Esquire
Michelle Mahan
Henry Meilman, M.D.
Lawrence Pinkner, M.D.
Frank Pommett, Jr.
Barry F. Rosen, Esquire
Joel Suldan, Esquire
Jack Tranter, Esquire
Terri Twilley, MS, RN
Douglas H. Wilson, Ph.D.

Task Force Members Absent

Commissioner Larry Ginsburg
Hal Cohen, Ph.D.
Anil K. Narang, D.O.
Christine M. Stefanides, RN, CHE

Members of the Public Present

Carla Bailey, Maryland Institute for Emergency Medical Services Systems (MIEMSS)
Clarence Brewton, MedStar Health
Andrew Cohen, AGC and Associates

Miles Cole, Maryland Department of Business and Economic Development
Carolyn Core, Civista Health, Inc.
Richard Coughlan, Cohen, Rutherford + Knight
Jack Eller, Esquire, Ober, Kaler, Grimes, & Shriver
Sean Flanagan, St. Joseph Medical Center
Richard Gasparotti, Adams Management Services
Christopher Hall, Adventist Healthcare
Wynee Hawk, Greater Baltimore Medical Center
Anne Langley, Johns Hopkins Health System
Ann Mitchell, Montgomery Hospice
Frank Monius, MHA: Association of Maryland Hospitals & Health Systems
Martha Nathanson, LifeBridge Health
Vanessa Purnell, MedStar Health
Laura Resh, Carroll Hospital Center
Olivia Stewart, Jack Neil & Associates
Paula S. Widerlite, Adventist HealthCare
Greg Vasas, CareFirst Blue Cross Blue Shield of Maryland

1. Call to Order

Commission Chairman Stephen J. Salamon thanked the members of the Task Force for their service to the Commission and introduced the Commission's new Executive Director, Rex M. Cowdry, M.D.

Chairman Robert E. Nicolay noted his service as chair of the search committee that selected Dr. Cowdry, and welcomed him to the Commission. He then called the meeting to order at 1:10 p.m.

2. Approval of the Previous Minutes (June 23, 2005)

Chairman Nicolay noted that members have received copies of the minutes from the June 23, 2005 Task Force meeting, and that several members have commented on how comprehensively the minutes captured the extensive discussion and deliberation at the last meeting. He drew the attention of the Task Force members to two issues, one a correction, and the other a potential need for further clarification. The first of these is on page 17 of the June 23rd minutes, paragraph 4, which, instead referring to a "vote on Dr. [Lawrence] Pinkner's motion," should read "Commissioner [Larry] Ginsburg's motion." Chairman Nicolay asked staff to make that correction, and then asked Pamela Barclay, Deputy Director for Health Resources, to highlight the other area of the June 23rd minutes that may need clarification.

Ms. Barclay called Task Force members' attention to the discussion in the minutes on the Certificate of Need requirement for closures of non-hospital health care facilities.[1] Staff wanted

[1] Hospitals in jurisdictions with three or more hospitals are only required to notify the Commission and hold a public informational hearing before the closure of a hospital or a hospital medical service, while a hospital in a jurisdiction with one or two hospitals must receive an exemption from Certificate of Need from the Commission before such a closure.

to confirm that the consensus of the Task Force on this question was it favored retaining a notification requirement, but wanted to eliminate the requirement for Certificate of Need exemption, where it applies, and for the public hearing.

Chairman Nicolay asked if anyone had a different recollection of the discussion, or wanted to add anything to this section of the minutes; no one offered further comment on that issue. The Chairman recognized Jack Tranter, who asked for a correction to another item. Following a discussion near the end of the previous meeting, Mr. Tranter had concurred with Barry Rosen's observation that the Task Force should not decide whether to continue Certificate of Need coverage of burn care units in Maryland in the absence of Patricia M. C. Brown of the Johns Hopkins Health System (JHHS). The only burn care unit in Maryland is at the Johns Hopkins Bayview Medical Center, a JHHS member. Mr. Tranter noted that he then asked to change his vote in favor of removing the Certificate of Need requirement from burn care units to an abstention, and he asked that the minutes reflect that change.

Chairman Nicolay asked staff to change the draft minutes accordingly, and then asked for any other additions or corrections to the minutes of the June 23, 2005 Task Force meeting. Hearing none, he called for a motion to approve these minutes as corrected. The motion was seconded and carried.

3. Review and Discussion of the Public Comments Received on the CON Program

- **Recap of June 23, 2005 Meeting**

Chairman Nicolay began his recap of the June 23rd Task Force meeting by recalling the thoughtful and comprehensive debate on the issue of deregulating hospice programs from Certificate of Need review, and noted that he had scheduled the conclusion of that discussion for a future meeting, at member Lynn Bonde's request. He also noted that the Task Force had decided at that meeting that clinically related information technology should not require Certificate of Need review; counsel will determine if Commission statute needs a specific provision to that effect. Chairman Nicolay then observed that, while the Task Force has made good progress, much remains to discuss and decide upon, so he proposed to add two meetings to the schedule. In addition, responding to comments by a number of members who believed that they needed more background on the issues before the Task Force, the Chairman has decided to take a different approach to the remaining issues of Certificate of Need coverage and process that were raised in the Public Forum and subsequent written comments. Prior to consideration of each issue, the members will receive a brief working paper outlining its current statutory and regulatory requirements, and summarizing the views expressed in the public comment provided to the Task Force. As we conclude the discussion of each issue, we will vote in order to have a sense of the Task Force's view, in effect as a straw vote, since the Task Force will consider and vote on a final report with all of its proposed recommendations to the Commission, at the conclusion of its work in September.

- **Principles to Guide the CON Program**

The Chairman then moved to a consideration of the draft "Guiding Principles for the Maryland Certificate of Need Program," asking for members' thoughts and recommendations on this summary of what those who presented comments to the Task Force believe should be the fundamental framework and purpose of CON.

Ms. Brown of the Johns Hopkins Health System began by apologizing for not attending the previous meeting, and asked if the Task Force would apply the guiding principles under discussion today to some of the issues that it discussed and voted on at that meeting. She asked the Chairman if she should state for the record the position of her organization on the Task Force's decision with regard to Certificate of Need coverage for burn care units as part of the discussion on guiding principles. The Chairman asked that the Task Force now consider the Guiding Principles document, but assured Ms. Brown that she could address the burn care issue, and that the full Task Force would revisit its decision as part of the total package of recommendations it will forward to the Commission.

Task Force member Albert Blumberg, M.D. said that he hoped that the Task Force would – once it agreed upon these guiding principles – apply them both to the issues previously discussed, as well as to its future deliberations. With regard to the principle of Certificate of Need as a means of improving the quality of a health care service, he stated his view that Certificate of Need does not function in that way, that it functions as a requirement to meet in order to initiate a service, but cannot guarantee the quality or safety of that service. That is not the purview of this Commission and the CON process, but instead of the licensure process, which we discussed extensively at the last meeting. One could argue, he said, that the CON process allows an opportunity to create quality and safety standards, because without that commitment, a potential provider would probably not receive Certificate of Need approval. However, since the Commission is not the entity with responsibility for seeing that providers keep their commitment to meet quality standards, he wanted to see that particular principle reworded or eliminated.

Mr. Rosen disagreed, maintaining that the CON process is related to safety, particularly in the health care services where a demonstrable correlation exists between volume and the quality and safety, and therefore provides a legitimate reason to restrict the number of providers of that service. Dr. Blumberg responded that, in his view, it was impossible for a proposed new provider to predict its volume would be, and that through the Certificate of Need process, a provider just makes a commitment to meet a minimum volume standard. Mr. Rosen maintained that in some services, giving cardiac surgery and interventional cardiology as an example, scientific studies establish the volume levels associated with safe operation and good outcomes, and that, if projected numbers of cases fall below that number, a new program will not meet that volume standard. Providers below that number of cases should lose their Certificate of Need authority. In services where volume and safety are related, the CON process protects that relationship by restricting the number of providers, and new services should only be considered in areas of rapid population growth, since that growth indicates that a new service will meet those minimum volume thresholds.

Dr. Blumberg asked if Mr. Rosen's view of the volume-quality relationship also applied to the discussion at the previous meeting of the rationale for restricting new providers from entering any market in which the number of potential users of that service is finite – specifically cited in support of continuing Certificate of Need coverage of hospice services. Mr. Rosen affirmed that the volume-quality issue could also apply to hospice, although other considerations might, as well, such as access (the concern that more hospice providers would choose to serve wealthier or more populated areas) and the effect of unrestricted entry of new providers on the margins of existing providers, and thus their ability to serve their patients.

In support of Mr. Rosen's comments, Mr. Tranter reminded Dr. Blumberg of the successive Commission task forces and committees charged with examining the clinical research and evidence on the volume-quality correlation in cardiac surgery, which have determined that this benchmark should be set at 200 cases per year. This is the benchmark in the State Health Plan, which now provides that a proposed new program must demonstrate and document – through surveys of cases that cardiologists will refer, and other means – its ability to meet and stay at that level of surgical volume. The Plan also provides that, if your program drops below that volume-quality threshold, it must relinquish its Certificate of Need authority. This is just one example of where there is a quality element to the regulatory process.

Adam Kane observed that the underlying assumption in this part of the draft Guiding Principles -- that restricting access of new providers to a market improves quality – does not recognize another important relationship – that increasing competition can also promote quality. He suggested that the phrase "improve the quality and safety of these services" is too broad, since, in some services, other mechanisms may improve quality and safety. Mr. Kane suggested narrowing that part of the principles to focus on services with a strong nexus between volume and quality or safety.

Task Force member Annice Cody disagreed that the Certificate of Need process only promotes quality of care in health care services where quantitative research has confirmed a quality-volume connection. As part of the review process, applicants can demonstrate the quality of their services in various ways, and Certificate of Need reviews often compare competing applications according to the ways in which each proposes to address issues of quality and safety.

Henry Meilman, M.D. offered observations, related to several previous comments. First, he questioned whether the award of a Certificate of Need should be permanent, or, instead, whether the authority it confers should be periodically reviewed for adherence to representations of projected volumes and quality of care. The volume-quality relationship, certainly for cardiac services, is real, and those of us involved in that issue in this state are still grappling with how to measure outcomes in cardiovascular procedures. We have had many good ideas, including modeling a quality measurement system after the New England quality improvement project, but we certainly have a way to go to continue to improve outcomes on an ongoing basis. During the last consideration of open heart surgery-related bills in Annapolis, seven different hospitals thought they needed to provide open heart programs; clearly, adding seven new cardiac surgery programs to the denominator, and maintaining a static or decreasing number of cases as the numerator, could decrease average volumes over all programs. This would have profound

implications from a volume-quality perspective, and could affect the access of the indigent population in the cities to the service, seriously disrupting the provision of this service across the state. While Maryland's regulatory framework for this service may not be perfect, Dr. Meilman observed that -- in his experience at both a so-called "have-not" hospital and a hospital with a cardiac surgery program – the Certificate of Need program has predicted the need and designated the right programs, which have all succeeded, and developed into Top-100 programs nationwide.

Dr. Blumberg stated that, after listening to this discussion, the use of the word "improve" still seems inappropriate in the wording of the principle in question. While he considered suggesting the word "insure," that word also implies a role in what he sees as the ongoing function of the state's licensure program. He instead proposed changing the principle to state that Maryland's CON program should *promote* quality and safety of the health care services it covers, since that is what he thinks the CON process is doing.

Lynne Bonde spoke in support of Dr. Meilman's comments, which she believes clearly also apply to the regulation of hospice programs. The Certificate of Need review threshold for consideration of new hospices is a projection of 250 additional hospice clients in a given jurisdiction. That allows growth in provider numbers that maintains the level that existing providers can serve, maintains their survivability and maintains the quality. Whether we use the word improve or the word promote in our principle does not matter as much as maintaining the concept that quality of care is an important consideration.

Patty Brown agreed that the final wording is less important than the continued inclusion of quality of health care services as a fundamental principle in Certificate of Need review. She noted that, twenty years ago when she became involved in health planning issues, the staff of this Commission's predecessor agency believed strongly that it played a critical role in improving the quality of health care in the State of Maryland, and this was a responsibility that they did not simply relinquish to the State licensing agency. She questioned whether the Commission still believes it has a continuing responsibility and an important role to play in improving quality, through the standards it adopts in the State Health Plan. Without its quality improvement component, the purpose of the Plan comes into question, and, if the conclusion is that the Plan functions only to deal with the competitive aspects of the Certificate of Need program, Ms. Brown said, that represents a fundamental shift in the philosophy of the Commission over the years.

Dr. Meilman noted that the National Heart, Lung, and Blood Institute [of the National Institutes for Health] published a report on cardiovascular disease outcomes research, quoting the Institute of Medicine [of the National Academy of Sciences]. This report included a *Blueprint for Improving Health Care Delivery*, which identified six core goals for the future of American health care: safety, effectiveness, equity, efficiency, timeliness, and patient-centeredness. He observed that these were laudable goals and directly relevant to the Task Force's discussion on guiding principles for the Certificate of Need program.

Mr. Tranter suggested that before the Task Force decides, or even discusses further, these draft guiding principles, it would be useful for us to review what statute says, and what the legislature has clearly outlined as the Commission's responsibilities and proper focus. While

some may disagree on the principles set forth in the enabling statute, we should apply this analytical measuring stick to anything this group eventually agrees upon, and recommends to the Commission.

Ms. Barclay agreed that this would be helpful for the group, and suggested that staff bring back a revised draft of the Guiding Principles document, along with the statute's statement of the Commission's duties and responsibilities, to the next meeting of the Task Force. Alan Bedrick, M.D. asked if the Commission has a mission and a vision statement. Ms. Barclay replied that the Commission has an overall mission and vision statement, and, in each chapter of the State Health Plan, articulates the policies and principles behind the system goals and review standards applicable to each covered health care service. In developing the draft Guiding Principles, Ms. Barclay noted, staff focused entirely on the proposals by the six commenters who wanted the Task Force to consider re-examining the overall principles that should shape the Certificate of Need program.

Ms. Cody noted that one concern she had with the present draft was that it focused on the program's role in preventing negative events in the health care system, and not enough on promoting good things, on promoting positive public policy goals. Dr. Bedrick concurred with this, also wanting to see more emphasis on the positive effects that Certificate of Need can achieve in the provision of health care services.

Dr. Cowdry observed that the Commission's mission statement has breadth, but not specificity, espousing the general concepts of cost containment and quality of care, but silent on the details of how that should be accomplished, and how the Commission's role should relate to that of the health department and its administrations. He noted that a key priority for staff in the next year would be to examine how the Certificate of Need process relates to licensure, in its quality enforcement activities, and how it relates to the work of other key agencies, such as the health Services Cost Review Commission. Dr. Cowdry agreed with the previous comments urging an emphasis on positive outcomes, suggesting that the Task Force's decisions on whether to continue Certificate of Need coverage for a given service should seek a balance between the potential positive and negative effects of increased competition. The focus should be on whether a strong enough justification exists – in the potential impact of increased competition on the cost and quality of care -- to intervene with Certificate of Need. Mr. Tranter recalled the term "managed competition," often used in past discussions on these issues, to describe this ideal of a balance between regulation and competition.

Ms. Bonde said that it was extremely important not to omit access to care from this set of factors, and to consider the potential effects of increased competition will do to access to certain services by underserved otherwise vulnerable populations. Mr. Rosen said that this effort to re-examine and articulate the guiding principles behind the Certificate of Need program, within its statutory context, is arguably the most important work of the Task Force, because these principles will be reflected in future planning activities and regulatory decisions, making them more predictable and clear to the Commission's constituencies.

Chairman Nicolay said that he would work with staff to revise and refine the draft principles, and bring them back to the Task Force for further review. They will be part of the

entire package of recommendations on which the Task Force will vote, before forwarding them to the Commission in September.

- **Coverage by CON Review**
  -Obstetric Services
  -Home Health Agency Services

Chairman Nicolay then opened the Task Force's discussion on the summary table of issues involved in whether to continue Certificate of Need regulation of new inpatient obstetrics programs.

William Chester, M.D. expressed support for continuing to require Certificate of Need to establish new inpatient obstetrics programs, because he believes, based upon his anesthesiology practice at a hospital with a high-volume obstetrics program, that high volumes are critical to maintaining the skill level of obstetrics practitioners and staff. Maintaining program staff of sufficient size and expertise to provide the necessary back up to support a 24 hour-seven-day service is only sustainable in a large volume service. He also noted that, with regard to the challenges presented to obstetricians and their hospitals by rising malpractice insurance premiums, incidence of questionable outcomes are demonstrably lower in high-volume programs.

Dr. Bedrick stated that, on this issue, he represents the position adopted by the Maryland Chapter of the American Academy of Pediatrics, not Franklin Square Hospital Center, where he practices, or MedStar Health, its parent corporation. He urged that members bring their collective expertise to this issue and approach it from the perspective of good public health policy, not individual private interests. He pointed out that the annual number of births is projected to remain stable or decrease, which means that new programs can only reduce volumes at existing ones. In addition, increasing the number of obstetrics programs would only marginally improve access to these services, since more than 98 percent of Maryland women of childbearing age have access to an existing program within a 30-minute drive time. The negative effect of increasing the number of obstetrics programs would offset any marginal increase in access; chief among these would be further strain on already serious staffing shortages. He stated that the Fetus and Newborn Committee of the Maryland Chapter of the American Academy of Pediatrics voted unanimously to support continuation of Certificate of Need coverage for new obstetrics programs.

Douglas Wilson, Ph.D. noted that many categories of health personnel needed to operate an obstetrics program are in seriously short supply, including obstetricians themselves; he believed that the University of Maryland Medical School had no applicants last year for its OB residency program, since the specialty is particularly affected by the crisis in malpractice insurance costs. Dr. Wilson stated that further diluting an already too-small pool of professionals would be detrimental to the state, and so he would support maintaining the Certificate of Need requirement for this service.

Mr. Kane asked if staff could provide information on whether other states with Certificate of Need programs regulate this service. Chairman Nicolay noted that this information is in background materials previously distributed to the Task Force, the latest state surveys by the American Health Planning Association indicate that sixteen of the 37 states (plus the District of Columbia) with Certificate of Need programs require Certificate of Need to establish new OB programs. Mr. Kane then asked about the difference between the services provided by inpatient obstetrics programs versus freestanding birthing centers.

Dr. Bedrick explained these differences, in setting, staffing, equipment, and services offered. He explained that the small number of freestanding birthing centers in Maryland are staffed by nurse-midwives, and intended for mothers with low-risk pregnancies.

Mr. Kane then questioned the rationale for requiring Certificate of Need approval for new inpatient obstetrics programs, but only licensure for freestanding birthing centers. Dr. Bedrick responded that, because unforeseen situations may always arise during labor and delivery, and so proximity to and transfer agreements with acute care hospitals (for emergency Caesarian sections and neonatal specialty care) are crucial. Bad outcomes for infants result from delays in obtaining the higher level of care, which is only provided by an acute general hospital with obstetrics and pediatrics services.

Dr. Blumberg spoke against maintaining the Certificate of Need requirement for new OB services, since he believes that decisions to offer a medical service should be under the authority of a hospital's board of directors. He said that the fact that 170 women in labor reportedly came or were transported to North Arundel Hospital [recently renamed Baltimore-Washington Medical Center] was cause for concern. He noted that staffing shortages exist in all medical specialties, not only obstetrics, and that the major problem in OB is the shortage of obstetricians, because of the still-unresolved malpractice insurance crisis. Dr. Blumberg said that Certificate of Need regulation was unnecessary for this service, that the marketplace will regulate it.

Mr. Tranter began by disclosing his representation of the former North Arundel Hospital in Certificate of Need matters now pending before the Commission, including an application to establish a new obstetrics program. He argued that obstetrics is a basic hospital service, and that it makes no sense that North Arundel has established a birthing center across the street from the hospital by obtaining a license, but must obtain Certificate of Need approval before establishing an inpatient obstetrics service in the hospital. Licensing and JCAHO accreditation is sufficient to regulate obstetrics, pediatrics, and other basic services offered by acute care hospitals.

Dr. Pinkner stated his support for continuing to require Certificate of Need approval for new obstetrics units, since the process provides an opportunity for an applicant to demonstrate that a new service is needed. He asked why freestanding birthing centers may be established under Maryland law without Certificate of Need review. Ms. Barclay responded that Commission statute does not include freestanding birthing centers in its list of definitions of what constitutes a "health care facility" for purposes of Certificate of Need coverage. She explained that State licensing statute includes freestanding birthing centers in its umbrella definition "ambulatory care facilities," and noted that only five of these centers now operate in Maryland. A very small number of births take place in these freestanding centers -- on average,

substantially fewer than one thousand babies of the approximately 75,000 births typical of recent years. Ms. Barclay also noted that, since the North Arundel Hospital application is currently under review before the Commission, it would not be appropriate to comment further on anything specifically related to that matter.

Ms. Cody stated that the changes in the State Health Plan adopted specifically to guide the Commission's consideration of proposed new obstetrics services is beneficial, since it does not preclude approval of a new program in the context of stable or declining births, provided that the applicant can demonstrate a clear public benefit offered by the proposed program. Using the State Health Plan and the Certificate of Need process to achieve a public health benefit is consistent with the principles the Task Force discussed earlier.

Mr. Rosen noted that many comments to the Task Force cited the need to revise and update the State Health Plan, and that the different sections of the State Health Plan take different approaches to defining need and establishing standards used in Certificate of Need reviews for the service in question. He maintained that, as part of its mandate, the Task Force could advocate changes to the Plan, perhaps establishing as its consistent framework the balance among factors of costs and benefits described earlier by Dr. Cowdry.

Mr. Tranter referenced the earlier characterization by Ms. Cody and Ms. Barclay of the current State Health Plan for Obstetric Services, calling the different approach to the demonstration of need a positive step. The obstetrics as well as the cardiac surgery/interventional cardiology sections of the Plan have moved beyond simplistic, mathematical need projections, to a more complex balance between potential costs and potential benefits of approving a proposed new service. However, the issue remains, with regard to obstetrics, that a hospital needs Certificate of Need approval to establish a new service as fundamental to acute care as obstetrics, but may obtain a license and establish a freestanding birthing center across the street.

Dr. Bedrick described birthing centers as an anomaly in the system, suggesting that – despite some imperfections and inconsistencies in the way Maryland statute regulates the different levels of this service – we seek to improve the system, not discard it. He urged the Task Force to consider whether it should recommend adding freestanding birthing centers to those requiring Certificate of Need approval. Dr. Pinkner raised a similar point, asking if part of the Task Force's purview included recommending additional services for Certificate of Need coverage. Chairman Nicolay confirmed that the group could consider such a recommendation.

Carlessia A. Hussein, Dr.P.H. asked if the Commission has access to any outcomes data on births at freestanding birthing centers, as compared to Certificate of Need-regulated inpatient obstetrics settings at acute care hospitals. Her responsibilities at the state health department, related to quality of care and access disparities experienced by minority populations, include finding ways to address the persistent issue of infant mortality. Concern over the contributing causes of infant mortality and poor birth outcomes would seem to argue in favor of more management and oversight of new obstetrics services, not less.

Ms. Barclay responded that the state health department has some birth outcome data collected through the birth certificate registration process, but that she was not sure if that data is publicly available. Staff will obtain whatever data is available on this issue.

Dr. Chester noted that births at freestanding birthing centers are to a pre-screened group of mothers, a low-risk population, but that a significant degree of back-up and emergency transport must nevertheless be available. Obstetrics is not a basic service, and it is often a high-risk service. He stated his strong belief that the staffing availability issues are extremely important, and that there are "immeasurable benefits" to receiving care from teams of professionals in a high-volume hospital. These volumes are maintained by continuing the Certificate of Need coverage for this service.

Chairman Nicolay asked if the Task Force felt prepared to take a straw vote on this subject, which the group would then revisit when it considers its final report and recommendations to the Commission in September.

Mr. Kane asked if we have data from the states that do not regulate the establishment of new obstetrics services through Certificate of Need, with which we could compare the cost, outcomes, and availability of necessary staff, with Maryland's performance in those areas. Ms. Barclay replied that we do not have specific data from other states related to volumes, quality, or cost. Dr. Cowdry stated that staff would look for data and examine the literature to determine how strong a correlation exists, in obstetrics, between volumes and quality of care. He observed that if these benefits were not measurable, they might be questionable.

Dr. Chester replied that if one examined only the relatively absolute outcomes such as death, or lower Apgar scores, the benefits of a more experienced professional team working in a high-volume obstetrics program might not be quantifiable. However, he argued, in clinical situations requiring urgent decisions affecting the outcome of the pregnancy and the health of the newborn, a team with more experience will make better decisions. This is true even if that effect of those decisions is not immediately verifiable or readily measured.

Dr. Blumberg observed that he was unaware of any medical service in which experience did not increase expertise and quality of care, but that there are many areas of medical practice in professionals achieve and safeguard quality in the absence of the requirement of Certificate of Need approval. In addition, he said, he viewed the fact that 172 women in labor came or were brought to the emergency department at Baltimore-Washington Medical Center in FY 2004 as a failure of the Certificate of Need system, although, in this area, the real problem is how to convince a sub-population of women to get early and effective prenatal care.

Ms. Brown noted that encouraging the more effective and accessible provision of prenatal care could be accomplished through the State Health Plan. She expressed concern about what seems to be, in the context of this discussion, a selection among acute care services, of which to regulate and which to deregulate. She reminded the group that the Commission statute provides for Certificate of Need regulation of all acute care services, and said that nothing in the draft Guiding Principles document supports the selective deregulation of certain services within this general category. The only changes proposed to the fundamental statutory framework of

Certificate of Need coverage of acute care services have arisen from an entity's failure to receive Certificate of Need approval for a certain service. Ms. Brown applied the same principle, and had the same concern, about the tentative Task Force decision to single out burn care for deregulation, from among the specialized acute care services covered by Certificate of Need.

Ms. Barclay responded that the Task Force received comment from several persons and organizations on the issue of deregulating obstetrics from Certificate of Need review, which is why it is on the group's agenda for consideration.

Natalie Holland asked if, rather than consider a selective deregulation from Certificate of Need, it might be preferable to revise the State Health Plan to permit different ways to consider proposed new services. Ms. Barclay noted that the Commission's charge to the Task Force did not involve the specific consideration of comprehensive changes to the State Health Plan, but a more focused examination of the Certificate of Need process through which the Plan is implemented. Chairman Nicolay stated that the need to update the State Health Plan has been a recurrent theme among comments to and discussions among the Task Force, and that Commissioners and staff agreed that this is a priority.

Chairman Nicolay asked Dr. Chester if he had any data relevant to the volume-quality relationship in the provision of inpatient obstetrics services. Dr. Chester replied that he had pulled an article from the Journal of the American Society of Anesthesiologists that recommended the closure of low-volume obstetrics programs, but noted that the article did not include such data. He said that he would review literature and positions from the American College of Obstetrics and Gynecology (ACOG) and other organizations for relevant data.

Ms. Bonde noted that only one hospital (of the fourteen hospitals without an obstetrics program) has a Certificate of Need application pending to establish a new obstetrics service, and asked what the benefit would be to removing the Certificate of Need requirement. Joel Suldan stated that the Commission faces very challenging resource issues, and if deregulation of an individual service does not cause harm, Certificate of Need coverage should be discontinued for that service.

Chairman Nicolay ended discussion and called for the preliminary vote. Thirteen members voted to retain Certificate of Need coverage for new obstetric services (Bedrick, Bonde, Brown, Chester, Cody, Holland, Hussein, Mahan, Meilman, Pinkner, Rosen, Twilley, and Wilson) and six (Blumberg, Kane, Moffit, Pommett, Suldan, and Tranter) voted to eliminate this coverage.

The Chairman then moved the group to the consideration of whether to continue the Certificate of Need requirement to establish new home health agencies, and to expand existing agencies.

Terri Twilley began this discussion by noting that she represented an organization whose membership includes home care providers at all levels, including Medicare-certified home health agencies. Her organization is split on the question of retaining Certificate of Need coverage for this level of home health care, but clear in its view that, if Certificate of Need is retained, the

authority to operate an agency in specific jurisdictions should be enforced. Currently, there are many different levels of home care providers, and some, such as residential service agencies, are providing services that are reserved by licensure standards for home health agencies; this should be better enforced.

Dr. Blumberg said that he appreciated the very informative background paper on this service. He stated his position that the marketplace can do, and is doing, an adequate job of regulating the use of this service, through the stringent admission criteria enforced by Medicare, as the predominant payer. Mr. Kane agreed, adding that there is little capital cost to establishing a home health agency, and therefore minimal impact in the areas Certificate of Need has historically focused on.

Dr. Hussein asked Ms. Twilley if removing the Certificate of Need requirement would have a negative impact on quality of care by home health agencies. Ms. Twilley responded that the shortage of nurses and other professionals poses the greatest challenge to maintaining the quality of home health care, and that the Office of Health Care Quality (OHCQ), charged with enforcing licensure standards, is seriously overburdened.

Commissioner Robert Moffit concurred with Dr. Blumberg and Mr. Kane that Medicare regulations provide strict controls on the operation and utilization of home health agencies, whose services should be increasingly needed with the aging of the population. He observed that the federal government has tightened its control over home health agencies considerably in recent years, with more requirements and lower reimbursement. He noted that the imposition of increased duties and a prospective payment system in the Balanced Budget Act if 1997 resulted in the closure of 2,800 home health agencies nationwide. He advocated a greater degree of regulatory freedom for this sector of the health care delivery system.

Ms. Holland asked if an access to care problem exists for home health agency services. Ms. Barclay responded that all Maryland jurisdictions are served by at least one Medicare-certified agency. Ms. Bonde asked Ms. Twilley if the industry has considered the impact of deregulation from Certificate of Need coverage. Ms. Twilley replied that, because her organization represents home care providers in all categories, Certificate of Need-regulated and not regulated, opinions on the impact of deregulation vary accordingly.

Dr. Bedrick asked whether data that the Commission collects annually from existing home health agencies duplicates data collected under the Medicare-mandated OASIS program. Ms. Barclay responded that the Commission's annual survey elicits aggregate data from agencies on the number and the overall characteristics of clients served in each authorized jurisdiction.[2] The OASIS data collection instrument – put into place subsequent to the Commission's annual survey -- is much more detailed and extensive, and permits Medicare to assess the level and extent of care provided to home health agency clients, as well as to monitor quality of care issues. Commissioner Moffit described OASIS as an extensive tool to measure the quality of care provided by home health agencies. Ms. Bonde expressed concern that, in the absence of the initial review of quality-related capabilities provided by the Certificate of Need process, the

[2] The Office of Health Care Quality has historically considered this annual survey by the Commission the "annual report" required of home health agencies by licensing statute at §19-404(c)(6).

entire burden falls on the already-overburdened OHCQ, to enforce both licensure standards and Medicare Conditions of Participation, since OHCQ is Medicare's agent in Maryland. Ms. Twilley noted that OHCQ has responsibility for monitoring compliance with licensure standards by residential service agencies, but cannot adequately oversee that part of the home care sector.

Chairman Nicolay called for a preliminary vote on the question of whether to continue the Certificate of Need requirement for home health agencies. Five members voted to retain Certificate of Need coverage (Bedrick, Bonde, Cody, Pommett, and Wilson), three members abstained (Mahan, Tranter, Twilley), and eleven members voted to deregulate the service from Certificate of Need (Blumberg, Brown, Chester, Holland, Hussein, Kane, Meilman, Moffit, Pinkner, Rosen, and Suldan).

Chairman Nicolay recognized Ms. Brown, who wished to state her position (and that of the Johns Hopkins Health System) of opposition to removing the Certificate of Need requirement for burn care programs, thereby treating this service differently from the other specialized services regulated by Certificate of Need. She indicated her willingness to bring the Johns Hopkins Bayview Medical Center's new burn care director to address the Task Force, and noted that the director confirmed to her that significant issues exist in burn care, with respect to the relationship between volume and maintaining high quality of care. All of these specialized services now regulated through Certificate of Need – burn care, cardiac surgery, NICU, and transplant surgery -- share certain characteristics, most notably their high operating costs, and this correlation between volume of cases and high quality of care. Thankfully, because of the fire safety programs now in place, as a regional burn care center we struggle to maintain the case volumes required by our accreditation agency, the American Burn Association. We do not want to see duplication of these services.

Chairman Nicolay asked if Ms. Brown could supply a written position and further information, to be distributed to the Task Force, so that the Task Force could revisit this issue in a future meeting.

4. <u>Other Business</u>

- Future Meeting Schedule

Chairman Nicolay announced the addition of two meetings, on August 25 and September 8, 2005.

5. <u>Adjournment</u>

Dr. Wilson made a motion to adjourn, which Dr. Meilman seconded. The Task Force meeting adjourned at 3:00 p.m.